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HEALTH RESEARCH EXTENSION ACT OF 1985

OCTOBER 11, 1985.—Ordered to be printed

Filed under authority of the order of the Senate of OCTOBER 10 (legislative day, September 30), 1985

Mr. HATCH, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany H.R. 2409]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 2409) to amend the Public Health Service Act to revise and extend the authorities under that act relating to the National Institutes of Health and National Research Institutes, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment insert the following:

SECTION 1. SHORT TITLE; REFERENCE TO ACT; AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Health Research Extension Act of 1985".

(b) REFERENCE TO ACT.—Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be a reference to a section or other provision of the Public Health Service Act.

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SEC. 2. REVISION OF TITLE IV OF THE PUBLIC HEALTH SERVICE ACT.

Title IV of the Public Health Service Act is amended to read as follows:

"TITLE IV—NATIONAL RESEARCH INSTITUTES

"PART A—NATIONAL INSTITUTES OF HEALTH

"ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

"Sec. 401. (a) The National Institutes of Health is an agency of the Service.

"(b)(1) The following national research institutes are agencies of the National Institutes of Health:

"(A) The National Cancer Institute.

"(B) The National Heart, Lung, and Blood Institute.

"(C) The National Institute of Diabetes and Digestive and Kidney Diseases.

"(D) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

"(E) The National Institute on Aging.

"(F) The National Institute of Allergy and Infectious Diseases.

"(G) The National Institute of Child Health and Human Development.

"(H) The National Institute of Dental Research.

"(I) The National Eye Institute.

"(J) The National Institute of Neurological and Communicative Disorders and Stroke.

"(K) The National Institute of General Medical Sciences.

"(L) The National Institute of Environmental Health Sciences.

"(2) The following entities are agencies of the National Institutes of Health:

"(A) The National Library of Medicine.

"(B) The Division of Research Resources.

"(C) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

"(D) The National Center for Nursing Research.

"(c)(1) The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other programs with respect to any particular disease or groups of diseases or any other aspect of human health if—

"(A) the Secretary determines that an additional institute is necessary to carry out such activities; and

"(B) the additional institute is not established before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the determination made under subparagraph (A) with respect to the institute.

"(2) The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this paragraph before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the reorganization or abolition.

"(d) For purposes of this title, the term 'national research institute' means a national research institute listed in subsection (b) or established under subsection (c). A reference to the National Institutes of Health includes its agencies.

"APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

"SEC. 402. (a) The National Institutes of Health shall be headed by the Director of the National Institutes of Health (hereafter in this title referred to as the 'Director of NIH') who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

"(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

"(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

"(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

"(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 492;

"(4) for the national research institutes and administrative entities within the National Institutes of Health—

"(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

"(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

"(5) may secure resources for research conducted by or through the National Institutes of Health;

"(6) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

"(7) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

"(8) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

"(9) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

"(10) may accept voluntary and uncompensated services; and

"(11) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (6). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

"(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

"(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than two hundred experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

"(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

"(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

"(e) The Director of NIH shall—

"(1) advise the agencies of the National Institutes of Health on medical applications of research;

"(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

"(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information; and

"(4) monitor the effectiveness of the activities described in paragraph (3).

"(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities. The Associate Director shall annually report to the Director of NIH on the prevention activities undertaken by the Associate Director. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

"REPORT OF DIRECTOR OF NIH

"SEC. 403. The Secretary shall transmit to the President and to the Congress a biennial report which shall be prepared by the Director of NIH and which shall consist of—

"(1) a description of the activities carried out by and through the National Institutes of Health and the policies respecting the programs of the National Institutes of Health and such recommendations respecting such policies as the Secretary considers appropriate;

"(2) a description of the activities undertaken to improve grants and contracting accountability and technical and scientific peer review procedures of the National Institutes of Health and the national research institutes;

"(3) the reports made by the Associate Director for Prevention under section 402(f) during the period for which the biennial report is prepared; and

"(4) the biennial reports of the Directors of each of the national research institutes, the Director of the Division of Research Resources, and the Director of the National Center for Nursing Research.

The first report under this section shall be submitted not later than July 1, 1986, and shall relate to the fiscal year ending September 30, 1985. The next report shall be submitted not later than December 30, 1988, and shall relate to the two-fiscal-year period ending on the preceding September 30. Each subsequent report shall be submitted not later than 90 days after the end of the two-fiscal-year period for which the report is to be submitted.

"PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

"APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

"SEC. 405. (a) The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a national research institute shall report directly to the Director of NIH.

"(b)(1) In carrying out the purposes of section 301 with respect to the human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

"(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

"(i) the maintenance of health,

"(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

"(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

"(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

"(B) may, subject to the peer review prescribed under section 492(b) and any advisory council review under section 406(a)(3)(A)(i), conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

"(C) may conduct and support research training (i) for which fellowship support is not provided under section 487, and (ii) which is not residency training of physicians or other health professionals;

"(D) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

"(E) may develop, conduct, and support public and professional education and information programs;

"(F) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

"(G) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

"(H) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

"(I) may secure for the institute consultation services and advice of persons from the United States or abroad;

"(J) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

"(K) may accept voluntary and uncompensated services; and

"(L) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 2354, title 10, United States Code, shall apply with respect to contracts entered into under this subsection and section 402(b).

"(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

"(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 492; and

"(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

"(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492; and

"(ii) if the direct cost of the grant or cooperative agreement to be made exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 492 and is recommended under section 406(a)(3)(A)(ii) by the advisory council for the national research institute involved.

"(c) In carrying out subsection (b), each Director of a national research institute—

"(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

"(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute; and

"(3) may, with the approval of the advisory council for the institute and the Director of NIH, appoint technical and scientific peer review groups in addition to those appointed under section 402(b)(6).

"ADVISORY COUNCILS

"SEC. 406. (a)(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

"(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

"(3) Each advisory council for a national research institute—

"(A)(i) may on the basis of the materials provided under section 492(b)(2) respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

"(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 405(b)(2) and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

"(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

"(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the disease, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

"(C) may appoint subcommittees and convene workshops and conferences.

"(b)(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

"(2) The ex officio members of an advisory council shall consist of—

"(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established,

the Chief Medical Director of the Veterans' Administration or the Chief Dental Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

"(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

"(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

"(A) Two thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

"(B) One third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

"(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

"(c) The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

"(d) The chairman of an advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of the advisory council. The term of office of the chairman shall be two years.

"(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

"(f) The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the

advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

"(g) Each advisory council may prepare, for inclusion in the biennial report made under section 407, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

"(h)(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

"(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

"(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

"(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

"(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

"(i) appointments to such Board shall be made by the President;

"(ii) the term of office of an appointed member shall be 6 years;

"(iii) of the members appointed to the Board not less than five members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors);

"(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

"(v) the ex officio members of the Board shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Chief Medical Director of the Veterans' Administration, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers); and

"(vi) the Board shall meet at least four times each fiscal year.

"(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.

"BIENNIAL REPORT

"SEC. 407. The Director of each national research institute, after consultation with the advisory council for the institute, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the institute and program policies of the Director of the institute in the fiscal years respecting which the report is prepared. The Director of each national research institute may prepare such additional reports as the Director determines appropriate. The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments referred to in section 406(g).

"AUTHORIZATIONS OF APPROPRIATIONS

"SEC. 408. (a) In addition to amounts otherwise authorized to be appropriated under this title for the National Institutes of Health, the following amounts are authorized to be appropriated:

"(1)(A) For the National Cancer Institute (other than its programs under section 412), there are authorized to be appropriated $1,194,000,000 for fiscal year 1986, $1,270,000,000 for fiscal year 1987, and $1,344,000,000 for fiscal year 1988.

"(B) For the programs under section 412, there are authorized to be appropriated $68,000,000 for fiscal year 1986, $74,000,000 for fiscal year 1987, and $80,000,000 for fiscal year 1988.

"(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 419), there are authorized to be appropriated $809,000,000 for fiscal year 1986, $871,000,000 for fiscal year 1987, and $927,000,000 for fiscal year 1988. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

"(B) For the programs under section 419, there are authorized to be appropriated $82,000,000 for fiscal year 1986, $90,000 for fiscal year 1987, and $98,000 for fiscal year 1988.

"(b)(1) Except as provided in paragraph (2), the sum of the amounts obligated in any fiscal year for administrative expenses of the National Institutes of Health may not exceed an amount which is 5.5 percent of the total amount appropriated for such fiscal year for the National Institutes of Health.

"(2) Paragraph (1) does not apply to the National Library of Medicine, the National Center for Nursing Research, the John E. Fogarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

"(3) For purposes of paragraph (1), the term 'administrative expenses' means expenses incurred for the support of activitics rele-

vant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health. In identifying expenses incurred for such support and administration the Secretary shall consult with the Comptroller General of the United States.

"(4) Not later than December 31, 1987, and December 31 of each succeeding year, the Secretary shall report to the Congress the amount obligated in the fiscal year preceding such date for administrative expenses of the National Institutes of Health and the total amount appropriated for the National Institutes of Health for such fiscal year. The Secretary shall consult with the Comptroller General of the United States in preparing each report.

"PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

"Subpart 1—National Cancer Institute

"PURPOSE OF INSTITUTE

"SEC. 410. The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer and the continuing care of cancer patients and the families of cancer patients.

"NATIONAL CANCER PROGRAM

"SEC. 411. The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

"CANCER CONTROL PROGRAMS

"SEC. 412. The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

"(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—

"(A) the detection, diagnosis, prevention, and treatment of cancer,

"(B) the continuing care of cancer patients and the families of cancer patients, and

"(C) rehabilitation and counseling respecting cancer,

to physicians and other health professionals who provide care to individuals who have cancer;

"(2) the demonstration of and the education of students of the health professions and health professionals in—

"(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

"(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

"(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

"SPECIAL AUTHORITIES OF THE DIRECTOR

"SEC. 413. (a) The Director of the Institute shall establish an information and education center to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

"(b) The Director of the Institute in carrying out the National Cancer Program—

"(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

"(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

"(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education and training (including continuing education and laboratory and clinical research training);

"(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

"(5) may obtain (with the approval of the advisory council for the Institute and in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more

than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

"(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

"(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

"(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

"(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

"(8) may, subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution;

"(9) shall maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible through the use of information systems accessible to the public, general practitioners, and oncologic investigators, the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

"(10)(A) shall, notwithstanding section 405(a), prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council; and (B) may receive from the President and the Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by the Institute.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (5) unless the expert or consultant has agreed in writing to complete the entire period of the as-

signment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

"NATIONAL CANCER RESEARCH AND DEMONSTRATION CENTERS

"SEC. 414. (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer.

"(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

"(b) Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

"(1) construction (notwithstanding any limitation under section 496);

"(2) staffing and other basic operating costs, including such patient care costs as are required for research;

"(3) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

"(4) demonstration purposes.

As used in this paragraph, the term 'construction' does not include the acquisition of land, and the term 'training' does not include research training for which National Research Service Awards may be provided under section 487.

"(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

"PRESIDENT'S CANCER PANEL

"SEC. 415. (a)(1) The President's Cancer Panel (hereafter in this section referred to as the 'Panel') shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

"(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occur-

ring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term, and (ii) a member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

"(B) The President shall designate one of the members to serve as the chairman of the Panel for a term of one year.

"(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

"(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

"(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the National Cancer Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

"ASSOCIATE DIRECTOR FOR PREVENTION

"SEC. 416. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

"(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

"Subpart 2—National Heart, Lung, and Blood Institute

"PURPOSE OF THE INSTITUTE

"SEC. 418. The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

"HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASE PREVENTION AND CONTROL PROGRAMS

"SEC. 419. The Director of the Institute, under policies established by the Director of NIH and after consultation with the advisory council for the Institute, shall establish programs as necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children.

"INFORMATION AND EDUCATION

"SEC. 420. The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section the Director of the Institute shall place special emphasis upon—

"(1) the dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases; and

"(2) the dissemination of information designed to encourage children to adopt healthful habits respecting the risk factors related to the prevention of such diseases.

"NATIONAL HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES PROGRAM

"SEC. 421. (a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the 'Program') may provide for—

"(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

"(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

"(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

"(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of such diseases;

"(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

"(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

"(G) the education (including continuing education) and training of scientists, clinical investigators, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

"(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and the use of blood and blood products and the management of blood resources;

"(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

"(J) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

"(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

"(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

"(1) may, after approval of the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

"(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratory, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

"(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

"(C) may, in consultation with the advisory council for the Institute, acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

"(3) subject to section 405(b)(2) and without regard to section 3324 of title 31, United States Code, and section 3709 of the Revised Statutes (41 U.S.C. 5), may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions; and

"(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

"NATIONAL RESEARCH AND DEMONSTRATION CENTERS FOR HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES, SICKLE CELL ANEMIA, AND BLOOD RESOURCES

"SEC. 422. (a)(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

"(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

"(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children); and

"(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources.

"(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

"(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

"(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

"(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

"(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

"(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

"(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

"(b) The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

"(c)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

"(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

"(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

"(A) construction (notwithstanding any limitation under section 496);

"(B) staffing and other basic operating costs, including such patient care costs as are required for research;

"(C) training, including training for allied health professionals; and

"(D) demonstration purposes.

As used in this subsection, the term 'construction' does not include the acquisition of land, and the term 'training' does not include research training for which National Research Service Awards may be provided under section 487.

"(4) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

"INTERAGENCY TECHNICAL COMMITTEE

"SEC. 423. (a) The Secretary shall establish an Interagency Technical Committee on Heart, Blood Vessel, Lung and Blood Diseases and Blood Resources which shall be responsible for coordinating those aspects of all Federal health programs and activities relating to heart, blood vessel, lung, and blood diseases and blood resources to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

"(b) The Director of the Institute shall serve as chairman of the Committee and the Committee shall include representation from all Federal departments and agencies whose programs involve health functions or responsibilities relevant to the functions of the Committee, as determined by the Secretary.

"ASSOCIATE DIRECTOR FOR PREVENTION

"SEC. 424. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung, and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

"(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

"Subpart 3—National Institute of Diabetes and Digestive and Kidney Diseases

"PURPOSE OF THE INSTITUTE

"SEC. 426. The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

"DATA SYSTEMS AND INFORMATION CLEARINGHOUSES

"SEC. 427. (a) The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

"(b) The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

"(c) The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and urologic diseases and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

"DIVISION DIRECTORS FOR DIABETES, ENDOCRINOLOGY, AND METABOLIC DISEASES, DIGESTIVE DISEASES AND NUTRITION, AND KIDNEY, UROLOGIC, AND HEMATOLOGIC DISEASES

"SEC. 428. (a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases. Such Division Di-

rectors, under the supervision of the Director of the Institute, shall be responsible for—

"(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

"(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

"(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

"(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

"(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) together with such comments and recommendations as the Director of the Institute determines appropriate.

"(b) The Director of the Institute, acting through the the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases, shall—

"(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 487) in the diagnosis, prevention, and treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

"(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

"INTERAGENCY COORDINATING COMMITTEES

"SEC. 429. (a) For the purpose of—

"(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

"(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Co-

ordinating Committee (hereafter in this section individually referred to as a 'Committee').

"(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Division Director of the Institute for the diseases for which the Committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

"(c) Each Committee shall prepare an annual report for—

"(1) the Secretary;

"(2) the Director of NIH; and

"(3) the Advisory Board established under section 430 for the diseases for which the Committee was established,

detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.

"ADVISORY BOARDS

"SEC. 430. (a) The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an 'Advisory Board').

"(b) Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

"(1) The Secretary shall appoint—

"(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

"(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

"(2)(A) The following shall be ex officio members of each Advisory Board:

"(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers

for Disease Control, the Chief Medical Director of the Veterans' Administration, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

"(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

"(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

"(c) Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

"(d) The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

"(e) The members of each Advisory Board shall select a chairman from among the appointed members.

"(f) The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

"(g) Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

"(h) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

"(1) review and evaluate the implementation of the plan (referred to in section 433) respecting the diseases with respect to

which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

"(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

"(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

"(i) In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

"(j) Each Advisory Board shall prepare an annual report for the Secretary which—

"(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

"(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

"(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year; and

"(4) contains the Advisory Board's recommendations (if any) for changes in the plan referred to in section 433.

"(k) Each Advisory Board shall expire on September 30, 1988.

"(l) The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after such date. The members of the Boards in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

"RESEARCH AND TRAINING CENTERS

"SEC. 431. (a)(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of cen-

ters for research and training in diabetes mellitus and related endocrine and metabolic diseases. Each center developed or expanded under this subsection shall—

"(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

"(B) conduct—

"(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

"(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such diseases and complications, and in research in diabetes; and

"(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

"(2) A center may use funds provided under paragraph (1) to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

"(b) Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

"(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

"(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

"(3) shall encourage research into and programs for—

"(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

"(B) model programs for cost effective and preventive patient care; and

"(C) training physicians and scientists in research on such diseases, disorders, and complications; and

"(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders and disseminate such research, studies, and data to the health care profession and to the public.

"(c) The Director shall provide for the development or substantial expansion of centers for research in kidney and urologic diseases. Each center developed or expanded under this subsection—

"(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting

such research qualifications as may be prescribed by the Secretary;

"(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

"(3) shall encourage research into and programs for—

"(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

"(B) model programs for cost effective and preventive patient care; and

"(C) training physicians and scientists in research on such diseases; and

"(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

"(d) Insofar as practicable, centers developed or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capabilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

"ADVISORY COUNCIL SUBCOMMITTEES

"SEC. 432. There are established within the advisory council for the Institute appointed under section 406 a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts that the subcommittees determine will best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

"BIENNIAL REPORT

"SEC. 433. The Director of the Institute shall prepare for inclusion in the biennial report made under section 407 a description of the Institute's activities—

"(1) under the current diabetes plan under the National Diabetes Mellitus Research and Education Act; and

"(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 431.

"Subpart 4—National Institute of Arthritis and Musculoskeletal and Skin Diseases

"PURPOSE OF THE INSTITUTE

"SEC. 435. The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases, including sports-related disorders.

"NATIONAL ARTHRITIS AND MUSCULOSKELETAL DISEASES PROGRAM

"SEC. 436. (a) The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal diseases. The plan shall include such comments and recommendations as the Director of the Institutes determines appropriate. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

"(b) Activities under the national arthritis and musculoskeletal diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal diseases, and shall, at least, provide for—

"(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal diseases;

"(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation and prevention of arthritis and musculoskeletal diseases;

"(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for

damaged bone, muscle, and joints and other supporting structures; and

"(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields.

"(c) The Director of the Institute shall carry out the national arthritis and musculoskeletal diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

"RESEARCH AND TRAINING

"SEC. 437. The Director of the Institute shall—

"(1) carry out programs of support for research and training (other than training for which National Research Service Awards may be made under section 487) in the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

"(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

"DATA SYSTEM AND INFORMATION CLEARINGHOUSE

"SEC. 438. (a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases.

"(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases by health professionals, patients, and the public.

"INTERAGENCY COORDINATING COMMITTEES

"SEC. 439. (a) For the purpose of—

"(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

"(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a 'Committee').

"(b) Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

"(c) Not later than 120 days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a).

"ARTHRITIS AND MUSCULOSKELETAL DISEASES DEMONSTRATION PROJECTS

"SEC. 440. (a) The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 441, and the data system established under subsection (c).

"(b) Projects supported under this section shall include—

"(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

"(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

"(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

"(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

"(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

"(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

"(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

"(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

"(c) The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 441, and other persons engaged in arthritis and musculoskeletal disease programs.

"MULTIPURPOSE ARTHRITIS AND MUSCULOSKELETAL DISEASES CENTERS

"SEC. 441. (a) The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term 'modernization' means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

"(b) Each center assisted under this section shall—

"(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

"(2) conduct—

"(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

"(B) training programs for physicians, scientists, and other health and allied health professionals;

"(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

"(D) programs for the dissemination to the general public of information—

"(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

"(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

"(c) Each center assisted under this section may conduct programs to—

"(1) establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

"(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

"(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

"(d) The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

"(e) Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

"ADVISORY BOARD

"SEC. 442. (a) The Secretary shall establish in the Institute the National Arthritis Advisory Board (hereafter in this section referred to as the 'Advisory Board').

"(b) The Advisory Board shall be composed of eighteen appointed members and nonvoting, ex officio members, as follows:

"(1) The Secretary shall appoint—

"(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

"(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

"(2) The following shall be ex officio members of the Advisory Board:

"(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

"(B) such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

"(c) Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

"(d) The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

"(e) The members of the Advisory Board shall select a chairman from among the appointed members.

"(f) The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

"(g) The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

"(h) The Advisory Board shall—

"(1) review and evaluate the implementation of the plan prepared under section 436(a) and periodically update the plan to ensure its continuing relevance;

"(2) for the purpose of assuring the most effective use and organization of resources respecting arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to

the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

"(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 439, and with key non-Federal entities involved in activities affecting the control of such diseases.

"(i) In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

"(j) The Advisory Board shall prepare an annual report for the Secretary which—

"(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

"(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

"(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made; and

"(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a).

"(k) The National Arthritis Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such date. The member of the Board in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

"Subpart 5—National Institute on Aging

"PURPOSE OF THE INSTITUTE

"SEC. 443. The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the 'Institute') is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

"SPECIAL FUNCTIONS

"SEC. 444. (a) In carrying out the training responsibilities under this Act or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

"(b) The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

"(c) The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

"(d) The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer's Disease.

"ALZHEIMER'S DISEASE CENTERS

"SEC. 445. (a)(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's Disease.

"(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

"(b) Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

"(1) construction (notwithstanding any limitation under section 496);

"(2) staffing and other basic operating costs, including such patient care costs as are required for research;

"(3) training, including training for allied health professionals; and

"(4) demonstration purposes.

As used in this subsection, the term 'construction' does not include the acquisition of land, and the term 'training' does not include research training for which National Research Service Awards may be provided under section 487.

"(c) Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

"Subpart 6—National Institute of Allergy and Infectious Diseases

"PURPOSE OF THE INSTITUTE

"SEC. 446. The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research,

training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases.

"Subpart 7—National Institute of Child Health and Human Development

"PURPOSE OF THE INSTITUTE

"SEC. 448. The general purpose of the National Institute of Child Health and Human Development (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to maternal health, child health, mental retardation, human growth and development, including prenatal development, population research, and special health problems and requirements of mothers and children.

"SUDDEN INFANT DEATH SYNDROME

"SEC. 449. The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

"MENTAL RETARDATION RESEARCH

"SEC. 450. The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of mental retardation.

"ASSOCIATE DIRECTOR FOR PREVENTION

"SEC. 451. (a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

"(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 407 a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

"Subpart 8—National Institute of Dental Research

"PURPOSE OF THE INSTITUTE

"SEC. 453. The general purpose of the National Institute of Dental Research is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

"Subpart 9—National Eye Institute

"PURPOSE OF THE INSTITUTE

"SEC. 455. The general purpose of the National Eye Institute (hereafter in this subpart referred to as the 'Institute') is the conduct

and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. The Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

"Subpart 10—National Institute of Neurological and Communicative Disorders and Stroke

"PURPOSE OF THE INSTITUTE

"SEC. 457. The general purpose of the National Institute of Neurological and Communicative Disorders and Stroke (hereafter in this subpart referred to as the 'Institute') is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder, stroke, and disorders of human communication.

"SPINAL CORD REGENERATION RESEARCH

"SEC. 458. The Director of the Institute shall conduct and support research into spinal cord regeneration.

"BIOENGINEERING RESEARCH

"SEC. 459. The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

"Subpart 11—National Institute of General Medical Sciences

"PURPOSE OF THE INSTITUTE

"SEC. 461. The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

"Subpart 12—National Institute of Environmental Health Sciences

"PURPOSE OF THE INSTITUTE

"SEC. 463. The general purpose of the National Institute of Environmental Health Sciences is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

"PART D—NATIONAL LIBRARY OF MEDICINE

"Subpart 1—General Provisions

"PURPOSE, ESTABLISHMENT, AND FUNCTIONS OF THE NATIONAL LIBRARY OF MEDICINE

"SEC. 465. (a) In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the 'Library').

(b) The Secretary, through the Library and subject to subsection (d), shall—

"(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;

"(2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;

"(3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);

"(4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;

"(5) provide reference and research assistance; and

"(6) engage in such other activities as the Secretary determines appropriate and as the Library's resources permit.

"(c) The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

"(d)(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

"(A) provide copies of its publications or materials,

"(B) will make available its facilities for research, or

"(C) will make available its bibliographic, reference, or other services,

to public and private entities and individuals.

"(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

"(A) without charge as a public service,

"(B) upon a loan, exchange, or charge basis, or

"(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

"(e) Whenever the Secretary, with the advice of the Board of Regents, determines that—

"(1) in any geographic area of the United States there is no regional medical library adequate to serve such area;

"(2) under criteria prescribed for the administration of section 475, there is a need for a regional medical library to serve such area; and

"(3) because there is no medical library located in such area which, with financial assistance under section 475, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

"(f) Section 2101 shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

"(g) For purposes of this part, the terms 'medicine' and 'medical', except when used in section 466, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

"BOARD OF REGENTS

"SEC. 466. (a)(1)(A) The Board of Regents of the National Library of Medicine consists of ex officio members and ten members appointed by the Secretary.

"(B) The ex officio members are the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Chief Medical Director of the Veterans' Administration, the Dean of the Uniformed Services University of the Health Sciences, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, the Director of the National Agricultural Library, and the Librarian of Congress (or their designees).

"(C) The appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education.

"(2) The Board shall annually elect one of the appointed members to serve as chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

"(b) The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

"(c) Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall

be eligible for reappointment within one year after the end of the preceding term of such member.

"LIBRARY FACILITIES

"SEC. 467. There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library. The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for such buildings and facilities and to erect thereon, furnish, and equip such buildings and facilities. The amounts authorized to be appropriated by this section include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

"Subpart 2—Financial Assistance

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 469. For the purpose of grants and contracts under sections 472, 473, 474, 475, and 476, there are authorized to be appropriated $12,000,000 for fiscal year 1986, $13,000,000 for fiscal year 1987, and $14,000,000 for fiscal year 1988. Funds appropriated under this section shall remain available for such purposes until the end of the fiscal year immediately following the fiscal year for which they were appropriated.

"DEFINITIONS

"SEC. 470. As used in this subpart—

"(1) the term 'medical library' means a library related to the sciences related to health; and

"(2) the term 'sciences related to health' includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

"NATIONAL MEDICAL LIBRARIES ASSISTANCE ADVISORY BOARD

"SEC. 471. (a) The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the 'Board').

"(b) The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

"(c) The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

"(d) Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to re-

ceive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 208(c) when attending conferences, traveling, or serving at the request of the Secretary in connection with the Board's function under this section.

"GRANTS FOR TRAINING IN MEDICAL LIBRARY SCIENCES

"SEC. 472. The Secretary shall make grants—

"(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

"(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

"(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

"(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

"ASSISTANCE FOR SPECIAL SCIENTIFIC PROJECTS, AND FOR RESEARCH AND DEVELOPMENT IN MEDICAL LIBRARY SCIENCE AND RELATED FIELDS

"SEC. 473. (a) The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

"(b) The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

"GRANTS FOR ESTABLISHING, EXPANDING, AND IMPROVING THE BASIC RESOURCES OF MEDICAL LIBRARIES AND RELATED INSTRUMENTALITIES

"SEC. 474. (a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of

establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

"(1) the acquisition of books, journals, photographs, motion picture and other films, and other similar materials;

"(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

"(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

"(4) the introduction of new technologies in medical librarianship.

"(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

"(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

"(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

"(C) the type of supportive staffs, if any, available to such library or instrumentality;

"(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

"(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

"(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

"(2) Grants to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed $500,000.

"GRANTS AND CONTRACTS FOR ESTABLISHMENT OF REGIONAL MEDICAL LIBRARIES

"SEC. 475. (a) The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

"(b) The uses for which grants and contracts under this section may be employed include the—

"(1) acquisition of books, journals, and other similar materials;

"(2) cataloging, binding, and other procedures for processing library resource materials for use by those who are served by the library;

"(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

"(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and

"(5) planning for services and activities under this section.

"(c)(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—

"(A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and

"(B) to provide free loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

"(2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—

"(A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and

"(B) the size and nature of the population to be served in the region in which the library is located.

"(d) Grants and contracts under this section for basic resource materials to a library may not exceed—

"(1) 50 percent of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or

"(2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

"FINANCIAL SUPPORT OF BIOMEDICAL SCIENTIFIC PUBLICATIONS

"SEC. 476. (a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing,

editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

"(b) Grants under subsection (a) in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of subsection (a).

"GRANT PAYMENTS, RECORDS, AND AUDIT

"SEC. 477. (a) Payments under grants made under sections 472, 473, 474, 475, and 476 may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

"(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

"(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

"PART E—OTHER AGENCIES OF NIH

"Subpart 1—Division of Research Resources

"GENERAL PURPOSE

"SEC. 479. The general purpose of the Division of Research Resources is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.

"ADVISORY COUNCIL

"SEC. 480. (a)(1) The Secretary shall appoint an advisory council for the Division of Research Resources which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Division on matters related to the activities carried out by and through the Division and the policies respecting such activities.

"(2) The advisory council for the Division of Research Resources may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Division.

"(3) The advisory council for the Division—

"(A)(i) may make recommendations to the Director of the Division respecting research conducted at the Division,

"(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

"(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Division;

"(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Division is concerned and with the approval of the Director of the Division make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

"(C) may appoint subcommittees and convene workshops and conferences.

"(b)(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

"(2) The ex officio members of the advisory council shall consist of—

"(A) the Secretary, the Director of NIH, the Director of the Division of Research Resources, the Chief Medical Director of the Veterans' Administration, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

"(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

"(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

"(A) Two thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Division.

"(B) One third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

"(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule.

"(c) The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from

the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

"(d) The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Division of Research Resources to be the chairman of the advisory council. The term of office of the chairman shall be two years.

"(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the Division of Research Resources, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Division.

"(f) The Director of the Division of Research Resources shall designate a member of the staff of the Division to serve as the executive secretary of the advisory council. The Director of the Division shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Division shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

"(g) The advisory council may prepare, for inclusion in the biennial report made under section 481, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Division of Research Resources in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Division. The advisory council may prepare such additional reports as it may determine appropriate.

"(h) This section does not terminate the membership of the advisory council for the Division of Research Resources which was in existence on the date of enactment of the Health Research Extension Act of 1985. After such date—

"(1) the Secretary shall make appointments to such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

"(2) the advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

"(3) the Director of the Division of Research Resources shall perform for such advisory council the functions prescribed by this section.

"BIENNIAL REPORT

"SEC. 481. The Director of the Division of Research Resources, after consultation with the advisory council for the Division, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the Division and program policies of the Director of the Division in the fiscal years respecting which the report is prepared. The Director of the Division may prepare such additional reports as the

Director determines appropriate. The Director of the Division shall provide the advisory council of the Division an opportunity for the submission of the written comments referred to in section 480(g).

"Subpart 2—John E. Fogarty International Center for Advanced Study in the Health Sciences

"GENERAL PURPOSE

"SEC. 482. The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

"(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

"(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

"(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

"(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

"(5) receive foreign visitors to the National Institutes of Health.

"Subpart 3—National Center for Nursing Research

"PURPOSE OF THE CENTER

"SEC. 483. The general purpose of the National Center for Nursing Research (hereafter in this subpart referred to as the 'Center') is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.

"SPECIFIC AUTHORITIES

"SEC. 484. To carry out section 483, the Director of the Center may provide research training and instruction and establish, in the Center and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses. The Director of the Center may provide individuals receiving such training and instruction or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary. The Director may make grants to nonprofit institutions to provide such training and instruction and traineeships and fellowships.

"ADVISORY COUNCIL

"SEC. 485. (a)(1) The Secretary shall appoint an advisory council for the Center which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Center on

matters related to the activities carried out by and through the Center and the policies respecting such activities.

"(2) The advisory council for the Center may recommend to the Secretary acceptance, in accordance with section 2101, of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Center.

"(3) The advisory council for the Center—

"(A)(i) may make recommendations to the Director of the Center respecting research conducted at the Center,

"(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

"(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Center;

"(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Center is concerned and with the approval of the Director of the Center make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

"(C) may appoint subcommittees and convene workshops and conferences.

"(b)(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

"(2) The ex officio members of the advisory council shall consist of—

"(A) the Secretary, the Director of NIH, the Director of the Center, the Chief Nursing Officer of the Veterans' Administration, the Assistant Secretary of Defense for Health Affairs, the Director of the Division of Nursing of the Health Resources and Services Administration (or the designees of such officers), and

"(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

"(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

"(A) Two thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Center. Of the members appointed pursuant to this subparagraph, at least seven shall be professional nurses who are recognized experts in the area of clinical practice, education, or research.

"(B) One third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

"(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service

on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

"(c) The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

"(d) The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Center to be the chairman of the advisory council. The term of office of the chairman shall be two years.

"(e) The advisory council shall meet at the call of the chairman or upon the request of the Director of the Center, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Center.

"(f) The Director of the Center shall designate a member of the staff of the Center to serve as the executive secretary of the advisory council. The Director of the Center shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Center shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

"(g) The advisory council may prepare, for inclusion in the biennial report made under section 486, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Center in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Center. The advisory council may prepare such additional reports as it may determine appropriate.

"BIENNIAL REPORT

"SEC. 486. The Director of the Center after consultation with the advisory council for the Center, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the Center and program policies of the Director of the Center in the fiscal years respecting which the report is prepared. The Director of the Center may prepare such additional reports as the Director determines appropri-

ate. The Director of the Center shall provide the advisory council of the Center an opportunity for the submission of the written comments referred to in section 485(g).

"PART F—AWARDS AND TRAINING

"NATIONAL RESEARCH SERVICE AWARDS

"SEC. 487. (a)(1) The Secretary shall—

"(A) provide National Research Service Awards for—

"(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration are directed;

"(ii) training at the National Institutes of Health and at the Administration of individuals to undertake such research;

"(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

"(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research; and

"(B) make grants to public and nonprofit private institutions to enable such institutions to make National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions.

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration, as the case may be.

"(2) National Research Service Awards may not be used to support residency training of physicians and other health professionals.

"(3) In awarding National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

"(b)(1) No National Research Service Award may be made by the Secretary to any individual unless—

"(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

"(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

"(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regula-

tion require) by the institution at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

"(2) The making of grants under subsection (a)(1)(B) for National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

"(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

"(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed—

"(A) five years in the aggregate for pre-doctoral training; and

"(B) three years in the aggregate for post-doctoral training;

unless the Secretary for good cause shown waives the application of such limit to such individual.

"(5) National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

"(c)(1) Each individual who is awarded a National Research Service Award (other than an individual who is a pre-baccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

"(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment.

"(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

"(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi(t—s/t)$$

in which 'A' is the amount the United States is entitled to recover; 'ϕ' is the sum of the total amount paid under one or more National Research Service Awards to such individual; 't' is the total number of months in such individual's service obligation; and 's' is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

"(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

"(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

"(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

"(d) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $244,000,000 for fiscal year 1986, $260,000,000 for fiscal year 1987, and $275,000,000 for fiscal year 1988. Of the amounts appropriated under this subsection—

"(1) not less than 15 percent shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a)(1)(A);

"(2) not less than 50 percent shall be made available for grants under subsection (a)(1)(B) for National Research Service Awards;

"(3) one-half of one percent shall be made available for payments under National Research Service Awards which (A) are made to individuals affiliated with entities which have received grants or contracts under section 780, 784, or 786, and (B)

are for research in primary medical care; and one-half of one percent shall be made available for payments under National Research Service Awards made for health services research by the National Center for Health Services Research and Health Care Technology Assessment under section 304(a)(3); and

"(4) not more than 4 percent may be obligated for National Research Service Awards for periods of three months or less.

"VISITING SCIENTIST AWARDS

"SEC. 488. (a) The Secretary may make awards (hereafter in this section referred to as 'Visiting Scientist Awards') to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

"(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

"STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

"SEC. 487. (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

"(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

"(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act, at or through national research institutes under the National Institutes of Health and institutes under the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel;

"(3) identify the kinds of research positions available to and held by individuals completing such programs;

"(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

"(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

"(b)(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

"(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

"(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.

"(c) A report on the results of the study required under subsection (a) shall be submitted by the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least once every four years.

"PART G—GENERAL PROVISIONS

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 491. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

"(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

"(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

"PEER REVIEW REQUIREMENTS

"SEC. 492. (a)(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

"(A) applications made for grants and cooperative agreements under this Act for biomedical and behavioral research; and

"(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

"(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

"(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on the date of the date of enactment of the Health Research Extension Act of 1985 to grants under this Act for biomedical and behavioral research, and

"(B) to the extent practical, by technical and scientific peer review groups performing such review on or before such date,

and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3).

"(b) The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

"(1) the reviewing entity be provided a written description of the research to be reviewed, and

"(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity,

and shall authorize such review to be conducted by groups appointed under sections 402(b)(6) and 405(c)(3).

"PROTECTION AGAINST SCIENTIFIC FRAUD

"SEC. 493. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

"(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

"(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.

"(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such fraud.

"RESEARCH ON PUBLIC HEALTH EMERGENCIES

"SEC. 494. (a) If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Ad-

ministration, or the Director of the Centers for Disease Control, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

"(1) shall expedite the review by advisory councils under section 406 and by peer review groups under section 492 of applications for grants for research on such disease or disorder or proposals for contracts for such research;

"(2) shall exercise the authority in section 3709 of the Revised Statutes (41 U.S.C. 5) respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

"(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

"(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

"(b) Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.

"ANIMALS IN RESEARCH

"SEC. 495. (a) The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

"(1) The proper care of animals to be used in biomedical and behavioral research.

"(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

"(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

"(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

"(3) The organization and operation of animal care committees in accordance with subsection (b).

"(b)(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the National research institutes) to assure compliance with the guidelines established under subsection (a).

"(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall in-

clude at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

"(3) Each animal care committee of a research entity shall—

"(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semi-annually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

"(B) keep appropriate records of reviews conducted under subparagraph (A); and

"(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

"(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on the date of enactment this section—

"(1) assurances satisfactory to the Director of NIH that—

"(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

"(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

"(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

"(d) If the Director of NIH determines that—

"(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

"(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

"(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

"(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

"USE OF APPROPRIATIONS UNDER THIS TITLE

"SEC. 496. Appropriations to carry out the purposes of this title shall be available for the acquisition of land or the erection of buildings only if so specified. Such appropriations, unless otherwise expressly provided, may be expended in the District of Columbia for—

"(1) personal services;

"(2) stenographic recording and translating services;

"(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

"(4) rental;

"(5) supplies and equipment;

"(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

"(7) purchase, operation, and maintenance of passenger motor vehicles;

"(8) printing and binding (in addition to that otherwise provided by law); and

"(9) all other necessary expenses in carrying out this title.

Such appropriations may be expended by contract if deemed necessary, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

"GIFTS

"SEC. 497. The Secretary may, in accordance with section 2101, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations of $50,000 or over for the National Institutes of Health or a national research institute for carrying out the purposes of this title may be acknowledged by the establishment within the National Institutes of Health or national research institute of suitable memorials to the donors.

"FETAL RESEARCH

"SEC. 498. (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

"(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

"(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

"(b) In administering the regulations for the protection of human research subjects which—

"(1) apply to research conducted or supported by the Secretary;

"(2) involve living human fetuses in utero; and

"(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

"(c)(1) The Biomedical Ethics Advisory Committee appointed under section 381 shall conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of such part 46 (or any successor to such regulations). The Committee shall complete the study and report its findings to the Biomedical Ethics Board established under section 381 not later than the expiration of thirty months after the date of enactment of this section. The report shall include the recommendations, if any, of the Committee on the advisability of the authority for such a waiver and the circumstances under which such a waiver might be granted. The Biomedical Ethics Board shall transmit the report to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate.

"(2) During the thirty-six-month period beginning on the date of enactment of this section, the Secretary may not grant (under section 46.211 of part 45 of title 46 of the Code of Federal Regulations or any successor to such section) a modification or waiver for fetal research.

"(3) Effective October 31, 1988, paragraph (2) is repealed.

"CONSTRUCTION OF TITLE

"SEC. 499. This title shall not be construed as limiting (1) the functions or authority of the Secretary under section 301 or of any officer or agency of the United States, relating to the study, prevention, diagnosis, and treatment of any disease for which a separate national research institute is established under this title, or (2) the expenditure of any funds therefor.".

SEC. 3. CONFORMING AMENDMENTS.

(a) ADVISORY COUNCILS.—(1) The National Advisory Health Council established under section 217 is terminated.

(2) Section 217(a) (42 U.S.C. 218(a)) is amended—

(A) in the first sentence—

(i) by striking out "National Advisory Health Council, the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, and the National Advisory Dental Research Council" and inserting in lieu thereof "National Advisory Mental Health

Council and the National Advisory Council on Alcohol Abuse and Alcoholism"; and

(ii) by striking out "by the Surgeon General with the approval of the Secretary of Health, Education, and Welfare" and inserting in lieu thereof "by the Secretary";

(B) in the second sentence—

(i) by striking out "in the case of the National Advisory Health Council, are skilled in the sciences related to health, and";

(ii) by striking out "the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, the National Advisory Heart Council, and the National Advisory Dental Research Council" and inserting in lieu thereof "the National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism"; and

(iii) by striking out ", alcohol abuse and alcoholism, and dental diseases and conditions" and inserting in lieu thereof "and alcohol abuse and alcoholism"; and

(C) by striking out the third sentence.

(3) Subsection (b) of section 217 is repealed and subsections (c) through (e) and subsection (g) are redesignated as subsections (b) through (e), respectively.

(4) Section 222(c) (42 U.S.C. 217a(c)) is amended to read as follows:

"(c) Upon appointment of any such council or committee, the Secretary may delegate to such council or committee such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate.".

(5) Section 301(a) (42 U.S.C. 241(a)) is amended—

(A) in paragraph (3), by striking out "as are recommended" through "for such fiscal year" and inserting in lieu thereof "as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research"; and

(B) in paragraph (8), by striking out "recommendations of the National Advisory Health Council" through "as he deems" and inserting in lieu thereof "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers".

(6) Section 1122(a) (42 U.S.C. 300c–12(a)) is amended by striking out "under section 441".

(b) NATIONAL LIBRARY OF MEDICINE.—Parts I and J of title III are repealed.

(c) ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH RESEARCH.—Section 506 is amended by adding at the end the following:

"(e)(1) If the direct cost of a grant, cooperative agreement, or contract (described in subsection (a)) to be made does not exceed

$50,000, the Secretary may make such grant, cooperative agreement, or contract only if such grant, cooperative agreement, or contract is recommended after technical and scientific peer review required by regulations under subsections (a) and (b).

"(2) If the direct cost of a grant, cooperative agreement, or contract (described in subsection (a)) to be made exceeds $50,000, the Secretary may make such grant, cooperative agreement, or contract only if such grant, cooperative agreement, or contract is recommended—

"(A) after technical and scientific peer review required by regulations under subsections (a) and (b), and

"(B) by the National Advisory Council on Alcohol Abuse and Alcoholism, the National Advisory Council on Drug Abuse, or the National Mental Health Advisory Council, as is appropriate.".

(d) ORPHAN DRUG ACT.—Section 8(w) of the Orphan Drug Act (Public Law 97-414) is repealed.

SEC. 4. PLAN FOR RESEARCH INVOLVING ANIMALS.

(a) ESTABLISHMENT OF PLAN.—The Director of the National Institutes of Health shall establish a plan for—

(1) research to be conducted by or through the National Institutes of Health and the national research institutes into methods of biomedical research and experimentation—

(A) which do not require the use of animals;

(B) which reduce the number of animals used in such research; or

(C) which produce less pain and distress in such animals than methods currently in use;

(2) establishing the validity and reliability of the methods described in subparagraph (A);

(3) the development of such methods which have been found to be valid and reliable; and

(4) the training of scientists in the use of such methods.

The plan required by this paragraph shall be prepared not later than October 1, 1986.

(b) DISSEMINATION OF INFORMATION.—The Director of the National Institutes of Health shall take such actions as may be appropriate to convey to scientists and others involved with research or experimentation involving animals information respecting the methods found to be valid and reliable under subsection (a)(2).

(c) INTERAGENCY COORDINATING COMMITTEE.—The Director of the National Institutes of Health shall establish within the National Institutes of Health an Interagency Coordinating Committee to assist the Director of the National Institutes of Health in the development of the plan required by subsection (a). The Director of each national research institute shall serve on the Committee.

SEC. 5. RESEARCH ON LUPUS ERYTHEMATOSUS.

(a) ESTABLISHMENT OF COMMITTEE.—The Secretary shall establish a Lupus Erythematosus Coordinating Committee to plan, develop, coordinate, and implement comprehensive Federal initiatives in research on Lupus Erythematosus.

(b) COMMITTEE COMPOSITION AND MEETINGS.—(1) The Committee shall be composed of—

(A) the Director of the National Institute of Neurological and Communicative Disorders and Stroke (or the designee of such Director);

(B) the Director of the National Institute of Allergy and Infectious Diseases (or the designee of such Director);

(C) the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (or the designee of such Director);

(D) the Director of the National Institute of General Medical Sciences (or the designee of such Director);

(E) the Director of the National Heart, Lung, and Blood Institute (or the designee of such Director);

(F) the Director of the National Institute of Diabetes and Digestive and Kidney Diseases (or the designee of such Director); and

(G) the Director of the Centers for Disease Control (or the designee of such Director).

(2) The Committee shall meet at least four times a year. The Secretary shall designate as chairman of the Committee the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(c) REPORT.—The Committee shall prepare a report for Congress on its activities. The report shall include a description of research projects on Lupus Erythematosus conducted or supported by Federal agencies in the fiscal year for which the report is made, the nature and purpose of each such project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project. Such report shall be submitted not later than 18 months after the date of the date of enactment of this Act. The Committee shall terminate one month after the report is submitted.

SEC. 6. NATIONAL RESEARCH SERVICE AWARD STUDY.

The Secretary of Health and Human Services shall conduct a study of—

(1) the effect of the service obligation requirement of section 487(c) of the Public Health Service Act on the number and quality of individuals who apply for National Research Service Awards;

(2) the effect of section 487(c)(4) of such Act on the number of persons who engage in health research or training as a career;

(3) the number of persons who receive National Research Service Awards and who engage in health research or training as a career; and

(4) the effectiveness of the grant authority under section 487(a)(1)(B) of such Act in encouraging individuals to engage in health research and training as a career.

The Secretary shall complete the study within one year after the date of enactment of this Act and shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

SEC. 7. INTERAGENCY COMMITTEE ON SPINAL CORD INJURY.

(a) ESTABLISHMENT.—Within 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall establish in the National Institute of Neurological and Communicative Diseases and Stroke an Interagency Committee on Spinal Cord Injury (hereafter in this section referred to as the "Interagency Committee"). The Interagency Committee shall plan, develop, coordinate, and implement comprehensive Federal initiatives in research on spinal cord injury and regeneration.

(b) COMMITTEE COMPOSITION AND MEETINGS.—(1) The Interagency Committee shall consist of representatives from—

(A) the National Institute on Neurological and Communicative Disorders and Stroke;

(B) the Department of Defense;

(C) the Department of Education;

(D) the Veterans' Administration;

(E) the Office of Science and Technology Policy; and

(F) the National Science Foundation;

designated by the heads of such entities.

(2) The Interagency Committee shall meet at least four times. The Secretary of Health and Human Services shall select the Chairman of the Interagency Committee from the members of the Interagency Committee.

(c) REPORT.—Within the 18 months after the date of enactment of this Act, the Interagency Committee shall prepare and transmit to the Congress a report concerning its activities under this section. The report shall include a description of research projects on spinal cord injury and regeneration conducted or supported by Federal agencies during such 18-month period, the nature and purpose of each such project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project.

(d) TERMINATION.—The Interagency Committee shall terminate 90 days after the date on which the Interagency Committee transmits the report required by subsection (c) to the Congress.

SEC. 8. STUDY OF PERSONNEL FOR HEALTH NEEDS OF THE ELDERLY.

(a) STUDY.—The Secretary shall conduct a study on the adequacy and availability of personnel to meet the current and projected health needs (including needs for home and community-based care) of elderly Americans through the year 2020.

(b) REPORT.—The Secretary shall report the results of the study to the Congress by March 1, 1987. The report on the study shall contain recommendations on—

(1) the number of primary care physicians, dentists, and other health personnel needed to provide adequate care for the elderly;

(2) the training needs of other physicians, dentists, and health personnel to provide care responsive to the particular needs of the elderly;

(3) necessary changes in medicare and other third party reimbursement programs necessary to support training of primary care and other physicians to meet the needs of the elderly; and

(4) necessary program changes in third party reimbursement programs (including changes in medicare programs) to support training of other health personnel in the care of the elderly.

SEC. 9. INTERAGENCY COMMITTEE ON LEARNING DISABILITIES.

(a) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Director of the National Institutes of Health shall establish an Interagency Committee on Learning Disabilities to review and assess Federal research priorities, activities, and findings regarding learning disabilities (including central nervous system dysfunction in children).

(b) COMPOSITION.—The Committee shall be composed of such representatives as the Director may designate, but shall include representatives from the National Institute of Neurological and Communicative Disorders and Stroke, the National Institute of Child Health and Human Development, the National Institute of Allergy and Infectious Diseases, the National Eye Institute, the National Institute of Environmental Health Sciences, the Division of Research Resources of the National Institutes of Health, the Food and Drug Administration, the National Institute of Mental Health, and the Department of Education.

(c) REPORT.—Not later than 18 months after the date of enactment of this Act, the Committee shall report to the Congress on its activities under subsection (a) and shall include in the report—

(1) the number of persons affected by learning disabilities and the demographic data which describes such persons;

(2) a description of the current research findings on the cause, diagnosis, treatment, and prevention of learning disabilities; and

(3) recommendations for legislation and administrative actions—

(A) to increase the effectiveness of research on learning disabilities and to improve the dissemination of the findings of such research; and

(B) respecting specific priorities for research in the cause, diagnosis, treatment, and prevention of learning disabilities.

(d) TERMINATION.—The Committee shall terminate 90 days after the date of the submission of the report under subsection (c).

SEC. 10. REVIEW OF DISEASE RESEARCH PROGRAMS OF THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES.

The Secretary of Health and Human Services shall conduct an administrative review of the disease research programs of the National Institute of Diabetes and Digestive and Kidney Diseases to determine if any of such programs could be more effectively and efficiently managed by other national research institutes. The Secretary shall complete such review within the one-year period beginning on the date of enactment of this Act.

SEC. 11. BIOMEDICAL ETHICS.

Title III (as amended by section 3) is amended by adding at the end the following:

"PART I—BIOMEDICAL ETHICS

"SEC. 381. (a) There is established in the legislative branch of the Government the Biomedical Ethics Board (hereinafter referred to as the 'Board').

"(b)(1) The Board shall consist of twelve members as follows:

"(A) Six Members of the Senate appointed as follows: Three members appointed by the Majority Leader of the Senate from the majority party and three members appointed by the Minority Leader from the minority party.

"(B) Six Members of the House of Representatives appointed by the Speaker of the House of Representatives, three from the majority party and three from the minority party.

"(2) The term of office of a member of the Board shall expire when the member leaves the office of Senator or Representative, as the case may be, or upon the expiration of eight years after the date of the member's appointment to the Board, whichever occurs first.

"(3) Vacancies in the membership of the Board shall not affect the power of the remaining members to execute the functions of the Board and shall be filled in the same manner as in the case of the original appointment.

"(4) The Board shall select a chairman and a vice chairman from among its members at the beginning of each Congress. The vice chairman shall act as chairman in the absence of the chairman or in the event of the incapacity of the chairman. The chairmanship and vice chairmanship shall alternate between the Senate and the House of Representatives with each Congress. The chairman during each even-numbered Congress shall be selected by the Members of the House of Representatives on the Board from among their number. The vice chairman during each Congress shall be chosen in the same manner from that House of Congress other than the House of Congress of which the chairman is a Member.

"(5) The Board shall meet once every three months unless such meeting is dispensed with by the chairman, and may meet at any time upon the request of four or more members of the Board or upon the call of the chairman.

"(c)(1) The Board shall study and report to the Congress on a continuing basis on the ethical issues arising from the delivery of health care and biomedical and behavioral research, including the protection of human subjects of such research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering.

"(2)(A) Except as provided in subparagraph (B), an annual report shall be transmitted to the Congress identifying the issues which were the subject of the study conducted under paragraph (1) and identifying areas, programs, and practices of medicine and biomedical and behavioral research which have significant ethical implications and which would be appropriate subjects for study.

"(B) A report on research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering shall be transmitted to the Congress not later than eighteen months after the appointment of the Committee under subsection (d).

"(d)(1) To conduct the studies and make the reports required by subsection (c), the Board shall appoint a Biomedical Ethics Advisory Committee (hereinafter referred to as the 'Committee'). The Committee shall consist of fourteen members as follows:

"(A) Four of the members shall be appointed by the Board from individuals who are distinguished in biomedical or behavioral research.

"(B) Three of the members shall be appointed by the Board from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

"(C) Five of the members shall be appointed by the Board from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than the biomedical or behavioral sciences), the social sciences, the humanities, health administration, government, and public affairs.

"(D) Two of the members shall be appointed by the Board from individuals who are representatives of citizens with an interest in biomedical ethics but who possess no specific expertise.

"(2)(A) The Committee, by majority vote, shall elect from its members a chairman and a vice chairman and appoint an executive director who shall serve for such time and under such conditions as the Committee may prescribe. In the absence of the chairman, or in the event of the incapacity of the chairman, the vice chairman shall act as chairman.

"(B) The term of office of each member of the Committee shall be four years, except that any such member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term. Terms of the members shall be staggered so as to establish a rotating membership.

"(C) The members of the Committee shall receive no pay for their services as members of the Committee, but shall be allowed necessary travel expenses (or, in the alternative, mileage for use of privately owned vehicles and a per diem in lieu of subsistence at not to exceed the rate prescribed in sections 5702 and 5704 of title 5, United States Code) and other necessary expenses incurred by them in the performance of duties as a member of the Committee, without regard to the provisions of subchapter 1 of chapter 57 and section 5731 of title 5, United States Code, and regulations promulgated thereunder.

"(D) The executive director of the Committee, with the approval of the Committee, may employ such staff and consultants as necessary to prepare studies and reports for the Committee.

"(3)(A) The Committee may, for the purpose of carrying out its functions, hold such public hearings, sit and act at such times and places, and take such testimony, as the Committee considers appropriate.

"(B) Upon request of the Committee, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Committee to assist the Committee in carrying out its functions.

"(C) The Committee may secure directly from any department or agency of the United States information necessary to enable it to

carry out its functions. Upon request of the chairman of the Committee, the head of such department or agency shall furnish such information to the Committee.

"(D) The Committee may accept, use, and dispose of gifts or donations or services or property.

"(E) The Committee may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

"(e) To enable the Board and the Committee to carry out their functions there are authorized to be appropriated $2,000,000 for fiscal year 1986, $2,500,000 for fiscal year 1987, and $3,000,000 for fiscal year 1988.".

SEC. 12. ALZHEIMER'S DISEASE REGISTRY.

(a) GRANT AUTHORITY.— The Director of the National Institute on Aging may make a grant to develop a registry for the collection of epidemiological data about Alzheimer's disease and its incidence in the United States, to train personnel in the collection of such data, and for other matters respecting such disease.

(b) QUALIFICATIONS.—To qualify for a grant under subsection (a) an applicant shall—

(1) be an accredited school of medicine or public health which has expertise in the collection of epidemiological data about individuals with Alzheimer's disease and in the development of disease registries, and

(2) have access to a large patient population, including a patient population representative of diverse ethnic backgrounds.

(c) AUTHORIZATION.—For grants under subsection (a), there are authorized to be appropriated $2,500,000 which shall remain available until expended or through fiscal year 1989, whichever occurs first.

And the Senate agree to the same.

ORRIN G. HATCH,
DAN QUAYLE,
DON NICKLES,
EDWARD M. KENNEDY,
CHRIS DODD,
Managers on the Part of the Senate.

JOHN D. DINGELL,
HENRY A. WAXMAN,
JAMES SCHEUER,
EDWARD MADIGAN,
Managers on the Part of the House.

JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 2409) to amend the Public Health Service Act to revise and extend the authorities under that Act relating to the National Institutes of Health and National Research Institutes, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The Senate amendment struck out all of the House bill after the enacting clause and inserted a substitute text.

The House recedes from its disagreement to the amendment of the Senate with an amendment which is a substitute for the House bill and the Senate amendment. The difference between the House bill, the Senate amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

INTRODUCTORY STATEMENT

House and Senate conferees met to consider the text of H.R. 2409, as amended by the Senate amendment reflecting the provisions of S. 1309 which passed the Senate on July 19, 1985.

The purpose of the conference agreement is to preserve America's preeminence in medical research. The legislation does this by extending for three fiscal years the programs administered by the National Institutes of Health (NIH) and making technical revisions in the statutory authority for NIH programs.

The conference agreement extends the authorization of appropriations for the National Cancer Institute, the National Heart, Lung and Blood Institute, the National Library of Medicine's Medical Library Assistance Act and the National Research Service Awards Program. The NIH is also required to conduct and support research in Alzheimer's Disease, spinal cord regeneration, mental retardation and bioengineering as a means to overcome paralysis.

The conference agreement provides explicit statutory authority for the NIH and its institutes and agencies. In addition, while there are provisions under current law for the appointment of the NIH Director, no statutory duties are prescribed or assigned. By clarifying the authority of NIH in statute, the conference agreement recognizes the importance and permanence of the NIH and its institutes and agencies. The conferees believe that given the critical role of health research in understanding the causes of

human disease and the development of more effective treatments, this recognition is long overdue.

The conference agreement promotes the more effective and efficient management of the NIH by strengthening procedures for peer review of intramural research and the investigation of scientific misconduct involving NIH grantees.

The conference agreement authorizes the Secretary to establish additional national research institutes administratively and to reorganize or abolish unnecessary institutes after submitting a report, six months in advance of such changes, to the Committee on Energy and Commerce in the House and the Committee on Labor and Human Resources in the Senate. The agreement describes the method of appointment and delineates the authorities of the NIH Director.

The conferees have also agreed on the need to establish at long last the National Institute of Arthritis and Musculoskeletal and Skin Diseases. The new institute will provide a national focus on research into the cause and treatment of these widely prevalent, often debilitating and sometimes fatal diseases.

RECODIFICATION OF NIH AUTHORITY

The conferees note that the statutory authority of the NIH was last revised in 1944 and now requires technical revisions to provide consistent, coordinated authority for all of the national research institutes and associated programs. The recodification is a significant step in clarifying and delineating the research function of the national research institutes and other agencies of the NIH. This rewrite of the law does not change the general authority of the Secretary of Health and Human Services to conduct research, investigations, experiments, and demonstrations relating to physical and mental diseases provided under Section 301 of the Public Health Service Act.

ESTABLISHMENT OF NEW NATIONAL RESEARCH INSTITUTES

The conference agreement establishes a new National Institute of Arthritis and Musculoskeletal and Skin Diseases. Establishment of this new institute necessitates revisions in current law to also establish a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD). The conference agreement will assure ongoing and improved research efforts in these disease categories.

Arthritis is actually more than 100 different disorders which afflict some 49 million of our citizens and, along with skin disorders, collectively result in an extraordinary loss to our economy from lost productivity as well as from medical expense. The conferees agree with the motto of the Arthritis Foundation—"It's time we took arthritis seriously." This new institute will provide a major increased focus on arthritis and musculoskeletal and skin diseases.

The conferees note that there is much promise held by research devoted to finding a cure for diabetes. Youngsters who develop diabetes early in life may, in fact, be suffering the consequences of an infectious disease which could be entirely preventable. Persons who already have insulin-dependent diabetes may eventually be cured if improved methods of pancreatic cell transplantation can be found.

There is justifiable optimism about finding a cure for diabetes; we may dare to begin hoping that diabetes may soon join the ranks of other diseases which have become part of medical history.

Revisions made in the authorities of NIDDKD are necessary to assure that the three disease clusters have adequate and parallel authority to conduct and support necessary research and education activities. Accordingly, the conference agreement establishes in statute a new Interagency Coordinating Committee for Kidney, Urologic and Hematologic Diseases in addition to the existing committees for Diabetes Mellitus and for Digestive Diseases. In addition, a new Kidney and Urologic Diseases Advisory Board is created to parallel the National Diabetes Advisory Board and the National Digestive Diseases Advisory Board. The authorization for each advisory board is extended for three fiscal years and expires on September 30, 1988.

The conference agreement provides for establishment of research center programs for digestive diseases and related disorders and kidney and urologic diseases to parallel those for diabetes and related endocrine and metabolic diseases. The conferees intend that these new centers be developed on a timetable that will promote research endeavors of the highest quality.

Section 10 of the conference agreement requires the Secretary to conduct an administrative review of the disease research programs of NIDDKD to determine if any program might, from both scientific and management standpoints, be more effectively and efficiently administered by other existing NIH institutes.

In revising the authorities for the National Diabetes Advisory Board and the National Digestive Diseases Advisory Board, the conferees intend to give the Secretary broad discretion in determining which present members of these Boards will be reappointed for additional terms. The conferees expect that the Secretary will give full consideration to present Board members in making appointments to the Boards. Advisory Board members will be appointed to four year terms, although the Secretary may stagger the appointment of new members as permitted under the current Board charters and consistent with the rotational membership patterns of NIH advisory councils.

NATIONAL CENTER FOR NURSING RESEARCH

The House bill provided for the establishment of a National Institute of Nursing at the National Institutes of Health. The Senate amendment did not contain a similar provision.

The Senate receded to the House with an amendment establishing a National Center for Nursing Research located within the National Institutes of Health. The Center is intended to be administered in a fashion similar to the Fogarty International Center and will be headed by a Director. The Center is intended to provide a focal point for promoting the growth and quality of research related to nursing and patient care, to provide leadership to expand the pool of experienced nursing researchers and to promote closer interaction with other bases of health care research. The conferees intend that nursing research and research training activities supported by the Division of Nursing in the Health Resources and

Services Administration be transferred to the NIH's National Center for Nursing Research.

The conferees believe that nursing research should be included in the mainstream of scientific investigation. The conferees are convinced that a significant amount of our health care dollars could be saved if research related to improved patient care, patient education, and health promotion were substantially supported. The conferees believe nursing plays a vital role in the delivery of health care in many underserved areas and as such should play a significant role in health services research.

The conferees anticipate that the programs of the new Center will be directed primarily toward basic and applied research related to patient care, the promotion of health, the prevention of illness, and the understanding of individual, family, and community responses to acute and chronic illness and disability. Patient care research may also address ethical and public policy concerns that will have a profound effect on the delivery of patient care. The Center may sponsor training of nursing research personnel, career development of new and established scientists, evaluation of specific nursing interventions, dissemination of new information about nursing and health, and demonstrations of alternatives means of delivery of nursing care.

PEER REVIEW OF INTRAMURAL RESEARCH

The conference agreement requires the Director of NIH to establish procedures for periodic technical and scientific peer review of all intramural research conducted at the National Institutes of Health. It is not the conferees' intent that the review procedures for intramural research be the same as those for extramural research. The conferees recognize that there are significant differences between intramural and extramural activities. The conferees do not intend that the review procedures established by the Director rely on the extramural model of prospective peer review of research on a project-by-project basis as a condition for support of future work. Peer review of intramural research should consider the work—past, present and future—conducted by either an entire laboratory or section of a laboratory.

Peer review may encompass the research projects of several investigators. Peer review should be conducted and reported on to the Congress at regular intervals but not less than every three years. The conferees agreed that the Director of NIH should submit, as part of the biennial report required by section 403 of the Act, an analysis of the Institute's intramural peer review procedures.

The entity conducting the peer review of an intramural laboratory is to be provided a written description of the overall research to be reviewed prior to the time of the review. This written description should present the overall past accomplishment of the laboratory and its investigators since the last review was conducted. The written description might also present: the general aims, objectives and projected directions of the research projects to be conducted; appropriate background information on possible future research

projects; a brief summary of the general research plan; and an indication of the importance of the research projects.

An entity conducting peer review of intramural research is to provide the institute's advisory council with a written description of the research, the results of the review and the recommendations of the reviewing entity. The conference agreement authorizes, but does not require, the advisory council to make recommendations to the insitute director regarding intramural activities conducted by the institute.

The conferees note that the NIH has in place a review mechanism to evaluate its intramural research programs. Each institute has a Board of Scientific Counselors composed of outside scientists who meet two or three times a year to appraise the work of its laboratories and scientists. The written reports prepared by the Boards and submitted to the Institute Director summarize the research and the Boards' judgments of its quality. The reports are also reviewed by the Director and Deputy Director for Intramural Research of NIH. The bill's requirement that these reports be furnished to the appropriate National Advisory Council is intended to encourage Council members to review the Board's efforts in program evaluation.

REVIEW OF RESEARCH CONTRACTS

Sections 490(a)(1)(B) and 405(b)(2) include provisions requiring technical and scientific peer review of applications for research contracts. The conferees long have recognized the invaluable role of peer review in ensuring high quality in the research activities funded and conducted by NIH. By referring to "contracts" and not to "contract projects" it is intended that peer review of research contracts not be limited to review at the concept-development phase. The conference agreement requires peer review and approval by peer review groups and all applications for research, training and demonstration contracts. It is expected that peer review by nonfederal employees will provide for more careful scrutiny of contracting practices by the national research institutes.

Regulations now require that agency heads, including the Director of NIH, "identify individual contracts or classes of contracts which may not be awarded unless all pertinent contract proposals have been reviewed by a peer review group . . ." It is not the conferees intent that scientific peer review of contracts for "research resources" such as the purchase of laboratory equipment, materials and supplies used in the conduct or support of research would be necessary. Such review is not required by these provisions.

BIENNIAL REPORT

The conference agreement consolidates current NIH reporting requirements to Congress by providing for the submission once every two years of a single, comprehensive report from the NIH Director. The conferees intend that the report be written, edited and organized in a manner that will assist the Congress in its oversight responsibilities, and that it be submitted on a timetable that will permit the report to be useful to the Congress.

The biennial report submitted by the NIH Director will contain separate reports from the Directors of each national research institute. Reports from the individual directors of the national research institutes should include reports from their respective advisory councils if the council desires to submit such a report. Comments included in the biennial report from the advisory councils of the individual national research institutes should present candid discussions of controversies regarding institute policies. The advisory council reports should indicate those research programs that its members consider to be no longer important to the missions of the institutes. Reports and comments from institute advisory councils should be submitted to Congress unchanged, except that comments by officials or officers of the government may be included as clearly identified and ascribed "additional views". Reports prepared by the Directors of the national research institutes under Section 407 should include an analysis of the rationale for the institute's policy recommendations and priorities as well as possible alternatives to policy recommendations considered or proposed by the advisory councils to the national research institutes.

The conferees do not intend that Section 407 of the revisions to Title IV be construed to prevent individual institute directors or advisory councils from reporting on their activities to the Congress on a more frequent basis, so long as they comply fully with the requirements of the biennial report. Section 407 and Section 406(g) authorize each institute director and advisory council to prepare, as they deem appropriate, additional reports to the Congress.

HEALTH PROMOTION AND DISEASE PREVENTION

The conferees believe it is time for NIH to place greater emphasis on research on health maintenance and the prevention of disease. To emphasize this aspect of the research spectrum, the conference agreement requires that the Director of the National Cancer Institute, the Director of the National Institute of Child Health and Human Development and the Director of NIH appoint an Associate Director for Prevention. A similar position is now provided by current law, and has functioned well for many years, in the National Heart, Lung and Blood Institute.

The conferees do not believe the position of Associate Director for Prevention at an individual institute should duplicate an existing administrative unit. Existing institute activities, programs and personnel involved with prevention activities should be incorporated, as appropriate, into a revised administrative framework.

Individuals appointed to these positions should be selected from among the nation's outstanding health promotion and public health professionals. They should not be appointed from those current NIH officials who have little or no background in the prevention field. Each Associate Director should devote full time to prevention-related activities and not have significant responsibilities for other non-prevention activities.

Among the principal responsibilities of the Associate Directors should be assuring that research regarding the prevention of disease is a high priority of their respective institutes. Prevention research refers to research that is directly related to reducing the in-

cidence of diseases or disorders within the authority of the respective national research institutes, reducing the high-risk precursors of such diseases or disorders, and reducing the adverse consequences of such precursors and early manifestations of such diseases or disorders.

The Associate Directors for Prevention should assure that each institute's research plan include sections dealing with such prevention related research as: investigations into the epidemiology of disease; studies of the etiology of diseases (including the effect of diet and other personal habits on the development of disease, and the effect of environmental factors, including air, water, radiation, and toxic substances, on the development of disease); research into immunizations against disease (particularly toward development of an improved pertussis vaccine); studies of the means to preclude the development of disease through changes in personal habits and environmental factors; and studies of methods for, and the cost-effectiveness of, population screening programs. The Associate Directors should submit recommendations annually to the Director of the institute for the specific activities and resources required by the institute to carry out the prevention-related activities.

The Associate Director for Prevention within the Office of the NIH Director has responsibility for promoting and coordinating the research programs of the national research institutes regarding the prevention of disease. The Associate Director is also responsible for coordinating NIH prevention activities with similar programs in other entities of the Department of Health and Human Services. The conferees believe the Associate Director should be a forceful, competent representative for research regarding the prevention of disease. In appointing the Associate Director, the Director of NIH should seek an individual from among the nation's outstanding public health and prevention researchers.

Although the conference agreement does not provide for establishment of a position of Associate Director for Prevention in all the national research institutes, each institute should give serious consideration to establishing such a position administratively.

Section 402(f) of the conference agreement requires the Associate Director to report annually to the Director of NIH on the prevention related activities undertaken during the previous year. Section 403 provides that these annual reports should be included in the NIH Director's biennial report to the Congress.

The conferees reduced the frequency of required NIH reports to biennial but have required the new reports on prevention activities to be submitted annually. The House Committee on Energy and Commerce and the Senate Committee on Labor and Human Resources will closely monitor these reports and the activities of the Associate Directors. It is the conferees intent to require this report on a biennial basis if it is evident that sufficient progress has been made in the prevention area.

ADVISORY COUNCILS

Section 406 of the conference agreement provides for the establishment of an advisory council consisting of up to 18 appointed members for each of the national research institutes. Currently,

each national research institute has an advisory council, established either by statute or by regulation, consisting of 12 to 18 appointed members.

The purpose of the advisory councils is to advise and consult with the Director of each national research institute on the complete spectrum of activities and policies of the institute. The conference agreement retains provisions of existing law requiring the Directors of national research institutes to consult with advisory councils in carrying out institute functions related to education and research. Advisory councils are also permitted to review intramural research and contracts, although this authority is optional and advisory council approval of contracts is not required.

As in existing law or regulation, advisory councils are required to review applications for grants and to recommend for approval those applications that show promise of making valuable contributions to human knowledge. Advisory councils may review any grant application, but are only requried to review those applications requesting over $50,000 in direct costs per annum. No grants with direct costs in excess of $50,000 may be awarded without approval of an Institute's Advisory Council. The conference agreement is consistent with but represents an increase of $15,000 over the existing statutory and administrative requirements that advisory councils review and approve all grants with direct costs in excess of $35,000.

Each advisory council may periodically review intramural research programs being carried out at the institute and make recommendations to the Director respecting such program. Based on materials provided to the advisory council pursuant to Section 490(b)(2) from entities charged with assessing the technical and scientific merits of intramural research, the advisory councils may review and make recommendations to the respective directors of the institutes regarding the importance and quality of the various intramural research programs.

Advisory council review of the intramural program under Section 406(a)(3)(A)(i) is not intended to be equivalent to advisory council review of grants and cooperative agreements. For example, while prospective advisory council review is required before grants are awarded, advisory council review of intramural work might be performed on a retrospective basis. The conferees believe advisory council review and recommendations can provide useful advice to the institute directors and the Director of NIH respecting the operation of the intramural program. Section 406 does not provide advisory councils approval authority over intramural research projects.

Section 406(b)(1) revises the composition of institute advisory councils to increase representation by experts in public health and the behavioral or social sciences. The membership of each advisory council must include two-thirds scientists with expertise in the disciplines of the respective institute and include experts in public health and the behavioral or social sciences. The remaining one-third should be from the general public who are knowledgeable with respect to diseases funded under the respective institutes, including leaders in such fields as social policy, law, health policy, economics and management. Ex officio members of the councils include the Secretary, the Director of NIH, the Director of the na-

tional research institute for which the council is established, the Chief Medical or Dental Director of the Veterans' Administration and the Assistant Secretary of Defense for Health Affairs.

It is intended that the chair of each advisory council be selected from among the appointed members. The director of a national research institute is not precluded from chairing an advisory council if the Secretary chooses to select the institute director. The Chairman of an advisory council may be reappointed.

The proposal also provides for staff assistance to the advisory councils and should include the services of an executive secretary to assist the council in its review of the activities and policies of the institute. The position of executive secretary need not be a full-time position, although some advisory council activities may require a greater allocation of staff resources than others. The functions of advisory councils will necessitate a minimum of three meetings per year and, in the case of the larger national research institutes, a minimum of four meetings per year.

NATIONAL CANCER INSTITUTE

The conference agreement revises and extends for three fiscal years the authorities for the National Cancer Institute. These sections are, for the most part, identical to provisions currently found in Sections 401 through 409 and commonly known as the "National Cancer Program." The conference agreement reemphasizes the importance of the National Cancer Act by maintaining the special authorities of the Director of the National Cancer Institute (NCI). The special authorities that have enabled the NCI to become one of the most productive of the national research institutes have been retained in their entirety. These authorities include the guidance of the President's Cancer Panel (Section 415), the submission of an annual budget request directly to the Congress (Section 413(b)(10)(A)) and the appointment of special peer review groups (Section 405(c)(3)) to evaluate the scientific merit of NCI research.

The conference agreement revises current law to extend the support period for cancer centers from three years to five years and removes the annual limitation on support for individual cancer centers.

The basic mission of the NCI was revised to require sponsorship of research on the continuing care of cancer patients and their families. The conferees agreed that a critical problem in cancer research is the growing number of patients suffering from cancer who seek alternative and unproven therapies when they have not responded to traditional methods of treatment. The cost and emotional suffering to dying patients and their families is significant. The conferees believe the Institute should give high priority to research related to the long term care of cancer patients and to the training of physicians in providing compassionate care to the terminally ill in addition to efforts to find cures and means of preventing malignant disease.

The proposal provides explicit authority under Section 412 for support of clinical cancer education programs. The achievements of these programs in medical and dental schools across the nation is well known and it is intended that support for such programs be

extended through fiscal year 1988. Activities funded under this authority are distinct from support for the training of future researchers under the provisions of the National Research Service Award Program. This section does not authorize NCI funds to be used in any way to support individuals, or institutions to operate residency or fellowship post-graduate physician programs in the various medical, surgical or other specialties or subspecialties.

The conferees also believe that the National Cancer Institute should increase the emphasis it places upon research on the relationship between diet and cancer. Under Section 416, one of the initial activities of the Associate Director for Prevention should be to conduct a thorough review of the current understanding of the relationship between diet and cancer, and consider appropriate means to increase NCI support for research in this area.

The conference agreement continues support for the NCI cancer center program. The conferees believe the centers program to be among the NCI's most important activities and that the Institute should expand the number of centers of excellence in underserved or demographically unique areas.

For example, the conferees recognize the lack of an organized, state-of-the-art cancer research and treatment center in the Appalachia region. It is estimated that about one-third of those West Virginians dying from cancer might have been saved by earlier diagnosis and treatment. The lack of organized statewide approaches to cancer prevention, detection, and accessibility to specialized care underscores the need for an academically based cancer center program for the State of West Virginia and the region of Appalachia that it would serve.

Another example of need is the state of Utah, which offers a number of specialized opportunities for cancer research. Scientific literature has documented that the Mormon population offers unique research opportunities in cancer prevention related to diet and nutrition. Low rates of cancer in this population appear to be related to specific dietary factors. Utah is also the site of exposure to low-level radiation which occured secondary to above ground testing of nuclear weapons in the 1940's and 1950's. Therefore, this state's population offers distinct opportunities for epidemiologic studies of the consequence of radiation exposure. Cancer screening is a logical extenson of this activity, and the establishment of a cancer center in Utah will assist in serving not only the state, but the central northwest region of the country, by providing treatment now unavailable to patients in large rural areas in this region of the country.

NATIONAL RESEARCH SERVICE AWARDS

The conference agreement emphasizes the importance of a continued commitment to the research training programs necessary to ensure an adequate number of able, highly trained investigators. New scientists are essential to continue the excellence of this country's biomedical, behavioral and health services research programs into the next century. The success of the nation's research program is closely tied to the number and quality of young professionals choosing research as a career. Since 1974, the National Research

Service Award (NRSA) program has been a vital part of the Federal effort to support the quality and integrity of biomedical and behavioral research.

Subsection 485(d) authorizes appropriations for NRSA awards and requires that portions of such appropriations be allocated for four specific programs. These authorizations for NRSA appropriations are $244 million in fiscal year 1986, $260 million in 1987 and $275 million in 1988. The following mandatory set-asides apply to funds appropriated under this authority: (1) Not less than 15% individual investigator awards; (2) Not less than 50% for institutional awards; (3) One-half of one percent for awards in family medicine and primary care; and (4) one-half of one percent for awards in health services research under the auspices of the National Center for Health Services Research and Health Care Technology Assessment. Thus, if in fiscal year 1986 the full $244 million authorized were appropriated, not less than $36.6 million could be used only for individual investigator awards, not less than $122 million only for institutional awards, $1.22 million only for family medicine and primary care awards and $1.22 million only for health services research awards.

The conference agreement reflects a long overdue broadening of the health and scientific research disiplines whose trainees will benefit from the availability of research training opportunities. By placing a restriction on the provision of National Research Service Awards for individuals involved in family medicine, primary medical care and health services research, the conferees recognize that during Fiscal Years 1986, 1987 and 1988 the pool of such persons is likely to be limited. The requirement that one percent of NRSA appropriations be evenly divided between NRSAs for researchers in family medicine, primary care and health services research is intended to represent a strict floor and ceiling on use of NRSA awards for these purposes. Compliance with these requirements does not require additional appropriations.

It is intended that funds appropriated under this authority for National Research Service Awards be used for research training and not for the support of research for which funds are available under sections 405 and 408 of this Title.

The conference agreement also requires the Secretary to undertake a study of the NRSA program. A major focus of the study is to determine the effect of the payback requirement, both benefits and problems, on the number and quality of individuals who apply for National Research Service Awards and become career researchers.

FETAL RESEARCH

The conference agreement includes provisions to define the circumstances under which research involving living human fetuses may be conducted.

In the case of living human nonviable fetuses ex utero or living human fetuses for whom viability has not yet been determined, the Secretary may support only those research projects that (1) may enhance the well-being or meet the health needs of the fetus, (2) enhance the probability of the fetus' survival to viability, or (3) whose purpose is to develop important biomedical knowledge that

cannot be obtained by other means and that will pose no added risk of suffering, injury, or death to the fetus. This standard is to be applied equally to fetuses that are aborted spontaneously or by induced abortion. It is not the intention of the Conferees that the phrase "no added risk of suffering" be construed to restrict routine diagnostic or medical procedures, such as the drawing of blood, that may themselves involve transient pain but pose no risk to the fetus of long-term suffering or injury.

In the case of living human fetuses in utero, the agreement requires that the Secrtetary administer regulations regarding the standard of risk in such a manner that a fetus that is intended for abortion is exposed to no greater risk than that to which a fetus that is intended to be carried to term may be exposed.

The conference agreement further provides that the Biomedical Ethics Advisory Committee, created by this legislation, is to conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the current "minimal risk" standard (or any successor to this standard) in research involving fetuses. The Committee is to complete its report within thirty months of the enactment of this legislation and shall report its findings to the Biomedical Ethics Board. The Board is to transmit the Committee's report to the Secretary, as well as to the Senate Committee on Labor and Human Resources and the House Committee on Energy and Commerce. The Conferees note that while the charge to the Biomedical Ethics Advisory Committee is limited under this provision, that Committee is empowered under other provisons of this legislation to review and investigate other issues involving the protection of human subjects, including fetuses.

The conference agreement also prohibits the Secretary from granting a waiver of the requirements of current regulations regarding research that is of unknown or greater-than-minimal risk. In addition, the conference agreement does not prohibit the Secretary from revising any regulations in effect on the day prior to the enactment of this legislation, including the waiver provision. This prohibition is intended to last for three years and is repealed as of October 31, 1988.

BIOMEDICAL ETHICS

The conference agreement amends Title 3 of the Public Health Service Act to establish an independent Congressional Biomedical Ethics Board patterned after the Office of Technology Assessment. The activities of the Biomedical Ethics Board (Board) would be supported by a Biomedical Ethics Advisory Committee. The Board would examine a broad range of biomedical issues and report to the Congress and the public. Two studies are specifically mandated in the legislation: (1) an examination of the nature, advisability, and biomedical and ethical implications of exercising any waiver of existing Federal protections of human fetuses in research and (2) a study of the ethical implications of developments in genetic engineering for human genetic engineering. The legislation authorizes appropriations of $2 million for the activities of the Board in Fiscal Year 1986, $2.5 million in 1987 and $3.0 in 1988.

JOHN E. FOGARTY INTERNATIONAL CENTER

Section 483 of the conference agreement authorizes the John E. Fogarty International Center for Advanced Study in the Health Sciences to facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields. To do this the Fogarty Center will require appropriate facilities which the Director of NIH should make available for such purposes. The conferees believe such NIH facilities as the "Stone House" would be appropriate sites for such activities.

INSTITUTIONAL REVIEW BOARDS

Section 489 restates existing Section 474, which requires the Secretary, by regulation, to obtain assurances of Institutional Review Board (IRB) review of behavioral or biomedical research. Effective IRBs are an important safeguard against abuse of human subjects involved in federally assisted or conducted research or demonstration projects.

In 1974 and 1978 Congress created special commissions on biomedical and behavioral research to address concerns about the dangers associated with experiments and demonstrations conducted or supported by the Department of Health and Human Services or other Federal agencies. Commission recommendations serve as an official record on the issue of safeguards for human subjects. The Secretary of the Department of Health and Human Services was requird to accept the findings and recommendations of the commissions or give substantial reasons for rejecting their views. One basic safeguard in the resulting regulations is IRB review of research or demonstrations which may have an impact on the rights or benefits conferred by Federal law and which pose more than a minimal risk for subjects.

SCIENTIFIC MISCONDUCT

Published reports detailing instances of scientific misconduct by Federal research grantees are rare, but are of serious concern to the public, the Congress and scientific community. While such instances are relatively infrequent, they are destructive of the public trust so necessary for the continued growth and expansion of scientific inquiry and Federal support for health research. Biomedical research—particularly that supported with public funds—must be conducted with the highest ethical and intellectual standards.

At present, NIH's procedures regarding scientific misconduct are informal and investigations of specific cases of alleged scientific misconduct have been handled on an *ad hoc* basis. Even cases in which the subject of an NIH investigation has admitted wrongdoing, the agency has taken months, and in some cases over a year, to complete its reviews, announce its findings and impose sanctions. The current debarment process of the Department of Health and Human Services does not adequately meet the need of NIH for a prompt, fair response to allegations of misconduct.

The Director of NIH should now take appropriate steps to establish a system for standardizing investigative procedures and post-investigatory sanctions in this area. Section 491 requires the Direc-

tor of NIH to establish a process for responding promptly to information concerning scientific fraud and violations of the rights of human subjects. The Conferees expect the system established to supplement existing Department-wide debarment regulations. The system should include procedures for the recover of Federal funds when appropriate.

Section 4901 requires each institution which receives NIH funds to establish an administrative process to review reports of scientific fraud. The conferees note that an institution need not have a standing committee to review reports of misconduct. Such institutions must, however, have a formal mechanism to establish such a committee quickly to investigate specific reports of fraudulent activity. Many institutions will find it appropriate to establish a standing committee on scientific misconduct. It is not the intent of the conferees to specify in detail the requirements for institutional procedures, but rather to underscore the responsibility of awardees promptly to investigate and report evidence of misconduct in publicly funded research programs.

The conference agreement also requires institutions to report to the Secretary any investigation of scientific fraud at such time that it appears that the report is substantial. It is not the Conferee's intent that the institution conclude its investigation prior to notifying the NIH. The NIH has a substantial interest in preserving the integrity of the research it supports and accordingly should become involved in misconduct inquiries as soon as there is reasonable evidence that an allegation of scientific fraud is substantive. The conferees expect the Director of NIH to ensure that the provisions of this system are widely publicized within the scientific and lay community.

RESEARCH AND PUBLIC HEALTH EMERGENCIES

Section 492 provides authority for the Secretary to expedite NIH's response to a disease or disorder that constitutes a public health emergency. The mission of NIH is not generally the day-to-day control or treatment of disease. In the case of complex biomedical emergencies, however, the resources of NIH are sometimes necessary for the Public Health Service to provide a comprehensive response to threats to the public health.

In conducting or supporting research on diseases or disorders that create a health crisis, the routine reviews that have served NIH so well in its development of a strong and diverse research portfolio have resulted in inappropriate delays. The conference agreement requires the Secretary—after determining that a public health emergency exists—to expedite scientific peer review and advisory council review of research grants, exercise exigency contract authority, and disseminate relevant information.

The Secretary is also authorized to provide administrative supplemental increases to existing grants and contracts of up to 50 percent of the original amount of such grants and contracts. The conferees believe that administrative supplemental increases to scientists working on related questions are a particularly appropriate way to initiate quickly research concerning a public health emergency.

The Secretary should use all of the components of this authority to provide a strong research response to public health emergencies. In doing so, the Secretary should coordinate efforts of NIH with those of other agencies of the Public Health Service.

CARE AND TREATMENT OF ANIMALS IN RESEARCH

Section 493 provides certain conditions with respect to the proper care and treatment of animals used in research which must be met by institutions that conduct reseach supported by NIH.

For the past twenty years, institutions receiving NIH grants and contracts have been required to meet NIH guidelines regarding the treatment of laboratory animals. These guidelines are presently based on the "Guide for the Care and Use of Laboratory Animals" developed by the Institute of LaboratoryAnimal Resources of the National Research Council.

It is important to provide statutory authority and recognition for these requirements. In order to ensure professionally appropriate direction for these conditions, the guidelines should remain under the control and direction of the Director of the NIH.

Subsection (b) requires entities that receive NIH support for research involving animals to establish and maintain animal care committees to monitor care and treatment of animals used in research. The membership of these committees would consist of at least three members, of which one must be a veterinarian and one an individual with no financial ties to the institution. This "outside" member is intended to provide representation for the general community interest in the proper care and treatment of animals.

The animal care committees are responsible for reviewing semiannually the care and treatment of animals in all animal study areas and facilities for compliance with NIH guidelines, for keeping appropriate records of such reviews, and for certifying to NIH that such reviews have been conducted. Animal care committees must report violations of NIH guidelines first to their institutions and, if a violation continues, then to NIH. The committees must only cerfity to NIH that reviews have taken place. Paperwork and reporting requirements are therefore minimal.

The requirement to establish animal care committees is intended to provide the most constructive assurance that NIH guidelines for the care and treatment of animals are met. It is far preferable to place primary responsibility for assuring compliance with NIH guidelines on committees within institutions rather than relying on intrusive Federal inspections as is presently the case. Testimony presented to the Subcommittee on Health and the Environment indicates that the cost of complying with this requirement would be minimal because service on animal care committees in many institutions is voluntary.

Under subsection (b)(2), the Chief Executive Officer of each research institution is charged with the authority to appoint all members of the animal care committees. As a result, the committees will serve as a constructive element within their institutions. The animal care committees' role will be to assure compliance with the NIH guidelines. The animal care committees have no authority to interfere with research decisions, goals or methods. The commit-

tees have no authority to "second guess" or review the appropriateness of research. The authority of the committees is limited to review of the care and treatment of animals pursuant to guidelines established by the NIH.

The animal care committees are important because their presence will create an ongoing discussion within the nation's research institutions of sensitivity to the care and treatment of research animals. This ongoing process recognizes that such sensitivity cannot be captured in any set of rules, that standards of care will change in the future as science advances, and that the value of medical research requires such judgments to be professionally and scientifically sound. The consultation inherent in the review of the care and treatment of animals by animal care committees is essential. Within such a framework, the public can have confidence that the proper sensitivity, whatever the sensitivity may be, to the care and treatment of animals will occur.

Two out of three research institutions receiving NIH funds already have animal care committees. Further, many of the nation's most respected research institutions already include a veterinarian and an "outside" member on their animal care committees.

Under subsection (c) the Secretary, acting through the NIH Director, shall issue regulations requiring applicants for NIH funds to provide assurances that the applicant will meet the NIH guidelines for the care and treatment of animals and that the applicant's institution has an animal care committee. Applicants must also assure NIH of the availability of instruction at their institution in humane practices of animal care and in research methods that minimize the use of animals and limit animal distress. All applications for NIH support will include a statement of the reasons for using animals in the research project in order to allow peer review committees to consider possible alternatives to or duplication of research.

If NIH determines that a research entity is not meeting the guidelines, and if after notification of its noncompliance, no action is taken, subsection (d) provides that the Director of NIH shall suspend or revoke a grant or contract. Since all institutions will make a commitment to meet the guidelines, effective animal care committees will virtually eliminate the possibility of revocation of funds. Animal care committees and NIH should give research institutions and grant recipients maximum opportunity to correct any instances of noncompliance. However, if after appropriate notification and consultation, inappropriate activities continue, NIH is authorized to suspend funds or revoke grants and contracts under such conditions as the Director of NIH determines are appropriate.

Subsection (e) provides that no guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose trade secrets or commercial or financial information which is privileged or confidential. This provision is intended to prevent the improper disclosure of trade secrets and other confidential information. Guidelines established by the Secretary under subsection (a) and regulations promulgated by the Director of NIH under subsection (c), should affirm the authority of the Secretary to assure compliance with guidelines on the proper care and treatment of laboratory animals and assure that trade secrets or propri-

etary research information in the possession of a research entity is protected. The conferees do not intend that subsection (e) be applied so as to restrict effective functioning of the animal care committees or inhibit authorized NIH investigations into allegations of improper care or use of laboratory animals involved in research supported by the NIH.

These requirements are consistent with both the values of humane treatment of animals and criteria for high quality scientific research. Both are already common practices in many research institutions.

NATIONAL LIBRARY OF MEDICINE

Part D (Sections 468–480) of the conference agreement technically revises the existing statutory authority of the National Library of Medicine (NLM). In addition, the conference agreement extends the authorization of appropriations for the important programs of the Medical Library Assistance Act through Fiscal Year 1988. This will ensure the continuation of a coordinated national effort to establish library and information services to improve the dissemination of health knowledge.

The support provided by the conference agreement represents an investment in promoting rapid transfer of medical information. Such rapid transfer is essential to reduce the critical time lag between discovery and practice. The conferees believe the continuing "information explosion" calls for innovative methodologies, technologies and systems and trained manpower to meet the information needs of medical science.

Rapid advances in medical science and technology and in human genetics require the thoughtful attention of scholars and students who must explore and learn about the beneficial as well as potentially harmful consequences of these developments. Bioethical issues require in-depth attention, for clinical and educational purposes as well as for the purposes of scholarly activities. During the last four to five years, there has been an explosion of literature related to bioethics that is not readily available to interested parties throughout the United States and around the world.

The Director of NIH, acting through the National Library of Medicine or the national research institutes, should take steps to support the acquisition and dissemination of information on bioethical issues. Such steps might include providing support for a centralized referral center, including library resources, through which the public, scholars, theologians and health personnel may obtain ready access to information on bioethics.

A 1982 General Accounting Office study [HRD–82–66] reported on the National Library of Medicine's (NLM) pricing policies for MEDLARS services. That study concludes that the NLM's pricing policies for establishing user charges to recover costs associated with accessing the MEDLARS data bases are consistent with existing statutes and regulations. The present cost-sharing arrangement, wherein the Federal government supports the creation of the MEDLARS system and the users in the biomedical community pay the full costs to access the system, has been effective and should be continued.

Section 475(c) of the authority for the National Library of Medicine authorizes grants to medical libraries. Potential grantees must assure that they will provide free library loan services to qualified users. The conferees do not intend this requirement to be unduly burdensome but believe that libraries should be public institutions and that their services, to the extent practicable, should be available to the general public at no cost.

RESEARCH ON ALTERNATIVE RESEARCH METHODS

As a result of recent important advancements in the understanding of the mechanisms of cell biology, there is great potential for the development of new research methods. These methods would, in certain instances, provide more accurate research results and reduce the costs of research while concurrently reducing the number of laboratory animals required and reducing the pain and distress to animals involved in such research.

Research involving the use of animals should and will continue. Nevertheless, the development of non-animal research methods deserves the focused attention of the NIH. Section 4 of the conference agreement directs the Director of NIH to develop and implement a plan for research on research methods which do not require the use of animals, reduce the number of animals used in research or reduce the pain and distress of animals used in research. Some research in this area is presently supported by the National Toxicology Program administered by the National Institute of Environmental Health Sciences. Funds allocated pursuant to this new authority are intended to increase the prevent level of effort by NIH.

The conferees note that the NIH has recently received a report entitled "Models for Biomedical Research: A New Perspective" which was prepared by the National Academy of Sciences under NIH contract. This report should be of use to the Director of NIH in developing the plan called for in this section.

INTERAGENCY COMMITTEE ON SPINAL CORD INJURY

The conferees believe that research on spinal cord regeneration should receive more attention within the Federal government. The Federal government is the only entity capable of supporting a major effort to find a cure for spinal cord injury.

In 1980, the Council of State Vocational Rehabilitation Administrators testified before the Subcommittee on Health and the Environment that: "Much more research will be required to develop and perfect techniques and to determine how such regeneration can be applied in cases of traumatic spinal cord injury to humans, but the findings at this point are most encouraging. With adequate financial support to enable this research to continue and to expand, a cure may be possible."

Similarly, the National Spinal Cord Injury Foundation testified that more than $20 million will be needed each year to conduct the research to meet presently identified research opportunities.

In 1980, President Carter established an Interagency Task Force on Spinal Cord Injury to coordinate the programs of the various Federal agencies and to develop and implement Federal medical initiatives related to spinal cord injury. The conferees are disap-

pointed that this Task Force was not continued despite the continuing need for this kind of effort.

The conference agreement recognizes the need for Federal agencies to bring increased and concentrated attention to research on spinal cord injury. The section establishes a temporary Interagency Committee on Spinal Cord Injury to continue the work of the previous Task Force. This Interagency Committee is to be composed of representatives from the National Institute of Neurological and Communicative Disorders and Stroke, the Department of Defense, the Department of Education, the Veterans Administration, the Office of Science and Technology Policy and the National Science Foundation. The Interagency Committee is intended to prompt all Federal agencies to give research regarding spinal cord regeneration a higher priority as they set their research agendas. The Committee is directed to report to Congress on related research being conducted by the various agencies. The tenure of the Committee is time limited in order to give the Congress the opportunity to review its activities. The Committee will terminate 18 months after the effective date of this Act.

STUDY OF PERSONNEL TO MEET THE HEALTH NEEDS OF THE ELDERLY

The conference agreement requires the Secretary to conduct a study which will provide a description of the health personnel needed to meet the health needs of the elderly for the next four decades.

The rapidly increasing number of persons over 65, and especially of those over 75, has been accompanied by increasing demand both for general medical care and for care directed specifically to diseases of the aging. Unfortunately, there has been inadequate attention paid to the need to train doctors and other health professionals to deal with both those aspects of the health needs of the elderly.

The Subcommittee on Health and the Environment held a hearing on this issue in September 1981, to gain insight into the dimensions of the problem and to receive some ideas for its solution. Testimony indicated that the medical profession is indeed aware that a problem exists in ensuring an adequate number of doctors working with the elderly and providing appropriate training for doctors, both in primary care and in the specialties most often needed by the elderly. There are, however, many barriers to implementing needed changes.

Among those barriers are long-held negative attitudes about the elderly and patterns of reimbursement both for training and care, which support treatment for acute illnesses in a hospital. Much of the care of the elderly is for chronic conditions and many elderly need to be treated in settings other than hospitals.

Personnel other than physicians are vital to good treatment. Nurses and social workers, in particular, need to be trained to provide appropriate intervention to ensure high level health care.

This report is to be presented to the Congress by March 1, 1987. The report is to include recommendations for specific numbers of personnel that will be required, including primary care physicians,

psychiatrists and other physician specialists, as well as other health personnel.

There is growing recognition of the need to develop leadership cadres of teachers and researchers in geriatrics. The Secretary's report should indicate ways such individuals may be developed and whether current demonstrations such as long-term care gerontology centers and teaching nursing homes should be continued.

The study should include legislative and other policy recommendations necessary to assure the training of an adequate supply of health personnel to meet the expected health care needs of the elderly.

INTERAGENCY COMMITTEE ON LEARNING DISABILITIES

Over the past years, much of the research into learning disabilities has centered on the educational and behavioral aspects of the problem. Neurophysiological investigations are emerging as crucial to the understanding and treatment of this disorder. Learning disabilities are now seen as among the most complicated of neurological impairments. While the incidence of learning disabilities exceeds that of all other neurologically handicapping conditions, they often go unrecognized and are among the ones least researched. Many agencies within NIH are involved in neurophysiological research into some aspects of this dysfunction, as are several other government institutions, yet efforts are fragmented and information is neither shared nor integrated among the various research groups.

Therefore, the conference agreement mandates the Director of NIH to appoint a task force composed of members of national research institutes which have been involved in research efforts into learning disabilities. These include the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Environmental Health Sciences (NIEHS), and the Division of Research Resources (DRR) of NIH; the National Institute of Mental Health of the Alcohol, Drug Abuse, and Mental Health Administration; the Food and Drug Administration; and the Department of Education. The Director also may appoint others to the task force, including public members who have expertise and interest in this area. It is expected as well that appropriate representatives from the Centers for Disease Control and the Environmental Protection Agency will be included on the task force.

The role of this task force is to bring to the attention of Congress the best thinking in the field on the incidence of learning disabilities, and any available epidemiological information; current research findings into the cause, diagnosis and treatment of these disorders; and administrative and legislative recommendations to focus research efforts more clearly, and to disseminate research findings.

A report of the task force is due to be presented to Congress within 18 months of enactment and should include specific research priorities on learning disabilities to ensure that future ef-

forts represent the best thinking in the field. The task force is temporary and will terminate 90 days after the date of the submission of the report to Congress.

DIET THERAPY AND CHRONIC KIDNEY DISEASE

The conferees are encouraged with recent progress following up on a meeting of a panel of distinguished nephrologists convened by the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases to review the state of research on the role of diet therapy in the treatment of end stage renal disease. The panel concluded, in a May 1982 letter to the Secretary of Health and Human Services, that "there is a distinct possibility that nutritional therapy can significantly retard the progression of chronic renal failure, as well as reducing uremic symptoms." Following this report the institute issued a request for cooperative agreements to explore this possibility. The planning phase of this study is being completed.

The conferees continue to be interested in the scope of the work to be conducted. In particular, as extremely low-protein diets are studied, supplementation, not only with keto analogues but also with essential amino acids, should be considered, as it now appears will be the case. In addition, action on the nephrology panel's recommendation for studies on the effects of nutritional therapy upon growth, development and renal function in children has only recently been initiated. The conferees look forward to progress on these important studies, including the important issues related to renal failure in childhood.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

In the summer of 1981, a new syndrome of acquired immune deficiency syndrome (AIDS) was identified in the United States. The House Committee on Energy and Commerce first reported on the incidence of this disease in 1983, and by April of that year almost 1,400 cases had been identified and over 500 people had died. By 1985, the incidence of this disease has risen to frightening proportions. As of October 1985, some 14,000 cases have been identified and over 7,000 people have died.

The outbreak is continuing, with twenty to twenty-five new cases per day being reporting to the Centers for Disease Control (CDC). As yet, there is little knowledge of either the prevention or treatment of the disease.

The conferees anticipate that CDC will continue its epidemiological and laboratory investigations into the cause and scope of the outbreak. The conferees intend that NIH—in cooperation with CDC's investigation—undertake and significantly expand intramural and extramural multidisciplinary research on the nature of the immune deficiency and its treatment. Continued progress of the outbreak dictates a sense of urgency in supporting and conducting research into AIDS. The conferees intend that research funds be made available as quickly as possible, both through the provisions made by this legislation for research on public health emergencies and through routine research solicitations and proposals, as well as interagency agreements and contracts. NIH should act with dis-

patch in funding clinical trials on pharmaceutical agents which are promising as effective remedies for AIDS related illness.

SEXUALLY TRANSMITTED DISEASES

From information received in legislative and oversight hearings, the conferees have concluded that sexually transmitted diseases have become a major public health threat to this nation. In 1980 the National Institute of Allergy and Infectious Diseases Sexually Transmitted Diseases Study Group stated that more babies are affected each year by a sexually transmitted disease than children affected by polio during the entire polio epidemic.

The conferees are concerned that control of these diseases has been hampered by a lack of information and adequate diagnostic and treatment techniques regarding these diseases and by the lack of priority ascribed this area of investigation by NIH. Despite strong report language in appropriations bills each year, very little growth in research on these diseases has taken place, although their spread through the population has been rapid. The conferees intend that a strong, well-defined research program be developed and believe that the National Institute of Allergy and Infectious Diseases must begin to take a more aggressive and responsible posture in confronting this epidemic through basic and clinical investigation as well as prevention research strategies.

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